REMARKS

Amendments

Claims 1, 14, and 15 are amended to incorporate the recitations of claims 46, 47, and 48, respectively.

Rejection under 35 USC §112, first paragraph

Claims 15, 17, 19-22, 27-30, 39-43, 48, 51-53, 55, and 57-62 are rejected as allegedly lacking enablement. This rejection is respectfully traversed.

In the rejection, it is asserted that the specification does not describe that a synergistic effect will be observed when treating a BCR-ABL-negative leukemia. Method claims are inherently functional. In other words, the literal scope of the method claims encompass only those embodiments that achieve the specified function. See, e.g., *In re Angstadt*, 190 USPQ 214 (CCPA 1976) and *Dinn-Nguyen et al.,* 181 USPQ 46 (CCPA 1974). Thus, to the extent the rejection is asserting that the claims are directed to leukemias which are not treatable by the recited compounds, such embodiments are not within the literal scope of the claims.

An application disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken in compliance with the enabling requirement of the first paragraph 35 U.S.C. § 112, unless there is reason to doubt the objective truth of statements contained therein relied on for enabling support. *In re Brana, 51 F.3d 1560,* 34 USPQ2d 1436 (Fed. Cir. 1995). *Fiers v. Revel, 984 F.2d 1164,* 24 USPQ2d 1601 (Fed. Cir. 1993). Furthermore, as stated in *In re Marzocchi*, 169 USPQ 367, 369 (CCPA 1971), the PTO must have adequate support for its challenge to the credibility of applicants' statements of utility. See also *In re Bundy*, 209 USPQ 48 (CPA 1981).

Hence, to establish non-enablement, the rejection can not merely assert, for example, that Topaly et al. discloses that synergism was achieved when using imatinib mesylate in combination with certain chemotherapeutic agents for the treatment of certain leukemias, but no synergism was achieved for such combinations in the treatment of other leukemias. The rejection provides no rationale as to why one would extrapolate the achievement of synergy or the lack thereof for the combinations of agents studied by Topaly et al. to the combination of agents recited in applicants' claimed method.

Further, it is by now well settled law that to establish the requisite objective enablement under the 35 USC 112, first paragraph, an applicants' disclosure is not required to present specific test results such as *in vivo* or *in vitro* test results. All that is required under the statute is objective enablement. See, e.g., *Marzocchi et al.*, at 369:

> The first paragraph of §112 requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance.

The MPEP is also in agreement with the holding in *Marzocchi.* The MPEP states that "compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed." See MPEP § 2164.02.

The test for enablement is not whether any experimentation is needed but whether or not that experimentation is undue. See, e.g., *In re Angstad*t, 190 USPQ 214, 219 (CCPA 1976) in which the art involved (catalysis) was acknowledged to be unpredictable. Even a considerable amount of experimentation, or complex experimentation, is permissible if it is routine. See, e.g., *Ex parte Jackson,* 217 USPQ 804, 807 (POBA 1982) and *In re Wands*, 8 USPQ 2d 1400, 1404 (Fed. Cir. 1988).

In view of the above remarks, it is respectfully submitted that the rejection fails to present sufficient rationale to doubt the veracity of the statements regarding enablement presented in the specification. Withdrawal of the rejection is respectfully requested.

Rejection under 35 USC §103(a)

Claims 1, 7, 9, 10, 14, 15, 18, 19, 25-27, 30-32, 39-41, 43-45, 52, 54-57, and 60-62 are rejected as allegedly being obvious in view of Giles et al. in combination with Drucker et al., Fang et al., and Topaly et al. This rejection is respectfully traversed.

This rejection was not applied against claims 46-48. As noted above, claims 1, 14, and 15 are amended to incorporate the recitations of claims 46-48. Thus, the rejection is rendered moot. Withdrawal of the rejection is respectfully requested.

Obviousness-Type Double Patenting Rejection

Claims 15, 17-22, 26-30, 41-43, and 52-60 are rejected as allegedly being obvious in view of claims 1-5, 10-16, and 22-31 of Jolivet et al. (US 6,645,972). This rejection is respectfully traversed.

This rejection was not applied against claim 48. As noted above, claim 15 is amended to incorporate the recitations of claim 48. Thus, the rejection is rendered moot. Withdrawal of the rejection is respectfully requested.

Moreover, the rejection fails to set forth why the rejected claims are "obvious" in view of the stated claims of US '972. One cannot establish obviousness-type double patenting without first establishing obviousness. Merely asserting that the claims of a patent describe a genus that allegedly overlap the subject matter claimed in the application does not set forth a basis for obviousness under the law. It is well settled law that a genus does not necessarily render obvious species encompassed therein.

The rejection fails to set forth rationale as to why the subject matter recited in claims of US '972 renders obvious the subject matter recited in claims of the instant application. Withdrawal of the obviousness-type double patenting rejection is respectfully requested.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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